XVI. 510(k) Summary

Submitter:	Syncro Medical Innovations, Inc. 433 Cherry Street Lower Level Suite #6 Macon, GA 31201
Contact person:	Sabry A. Gabriel, M.D. Phone: (478)301-4093 Fax: (478)301-2045 e-mail: Gabriel_sa@mercer.edu
Date summary prepared:	6/14/02
Device trade name:	MagnaFlow® Magnetically Guided Enteral Feeding Tube
Device common name:	Enteral Feeding Tube
Device classification name:	Tube, Feeding at CFR 21 876.5980
Legally marketed devices to which the device is substantially equivalent:	K972437: Flexiflo Magnetically Guided Enteral Feeding Tube
Description of device: MagnaFlow®	The MagnaFlow® Magnetically Guided Enteral Feeding Tube system is intended for direct placement in the small bowel. The catheter functions as a conduit for enteral feeding for patients who cannot consume an adequate diet orally. The catheter has a magnet embedded in the distal tip, which through the use of an external magnet aids in catheter placement. When the external magnet is in close proximity to the catheter tip, a reed switch (located proximal to tube tip magnet) closes, causing an LED light (in manifold) to illuminate. That light indicates when the external magnet has captured the tube distal portion. The external magnet can steer the catheter through the stomach pyloric sphincter into the duodenum.
Intended use of the device.	This catheter is inserted orally or trans-nasally directly into the small bowel and is intended to provide nutrition, fluids, and medications directly into the intestinal tract.
Technological characteristics:	The proposed device has the same fundamental technological characteristics of the predicate devices and similar design, packaging, sterilization and labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2002

Sabry A. Gabriel, M.D.
CEO and President
Syncro Medical Innovations, Inc.
433 Cherry Street
Lower Level Suite #6
MACON GA 31201

Re: K021991
Trade/Device Name: MagnaFlow® Magnetically Guided Enteral Feeding Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: June 14, 2002
Received: June 18, 2002

Dear Dr. Gabriel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K02 1991

VIII. Indications for Use

The MagnaFlow® Magnetically Guided Enteral Feeding Tube functions as a conduit to facilitate enteral feeding, and may be used in pediatric, adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with a functioning gut who require short- to moderate-term feeding support, such as post-trauma patients, post-surgical patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exists, or may result, secondary to an underlying disease or condition.

Concurrance of CRDH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use

David G. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021991